# Practitioner's Docket No. MPI01-018P1RNM

U.S.S.N. 10/074,527

#### REMARKS

Applicants refer to an Advisory Action mailed on January 26, 2005 for the present application. In the Advisory Action, the Examiner refused to enter Applicants' Amendment and Response After Final Rejection filed on January 3, 2005, apparently for two reasons. Herein, Applicants address the two reasons raised by the Examiner for not entering the Amendment and Response. Additionally, Applicants request that the Examiner consider the following remarks and enter the Amendment and Response.

## Interview Summary

On February 1, 2005, the representative for the Applicants spoke by telephone with Examiner Rao. Specifically, the Examiner was asked for clarification of the Advisory Action and the next step. Examiner Rao confirmed that two reasons, in regard to claim 35 and claim 18, were the dominant reasons for not entering the Amendment and Response After Final Rejection filed on January 3, 2005. Examiner Rao agreed to consider arguments presented herein in response to the Advisory Action.

#### New Claim 35

In the Advisory Action, new claim 35 was one reason the Examiner refused to enter the Amendment and Response After Final Rejection filed on January 3, 2005. New claim 35 recites a fusion polypeptide and is dependent on claim 12. The highlighted issue raised by the Examiner is the alleged indefiniteness and lack of written description due to the lack of recitation of glycosyltransferase activity for the fusion polypeptide. Applicants respectfully rebut this issue.

Claim 35 is dependent on claim 12. Claim 12 recites three polypeptide embodiments. Each polypeptide embodiment of claim 12 recites glycosyltransferase activity for the polypeptide. Applicants believed that the dependency on claim 12 would impart the glycosyltransferase activity on the polypeptide recited in claim 35. If the Examiner disagrees with this belief, he is welcome to telephone the Applicants and discuss a suitable remedy, e.g. an amendment to claim 35, to resolve this issue.

#### Claim 18

In the Advisory Action, the Examiner stated that an enablement rejection for claim 18 would be maintained due to the lack of high stringency language for hybridization. Applicant respectfully rebuts that this is a maintained rejection.

The enablement rejection in the previous Final Rejection mailed on November 1, 2004 raised issues with the recitation of a polynucleotide which is 95% identical to SEQ ID NO:1 or 3, a polynucleotide which encodes a polypeptide with an amino acid sequence of at least 90% or 95% identity to SEQ ID NO:2 and having at least one activity selected from the group consisting of the ability to

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"glycosylate a target molecule," "the ability to bind a simple sugar," or "the ability to attach to a membrane," or polypeptides "comprising 285 contiguous amino acids of SEQ ID NO:2," or "comprising a glycosyltransferase domain." Applicants are unable to find the location in that rejection where the "hybridizes" term in claim 18 was raised as an issue. Furthermore, in the previous Office Action mailed on February 9, 2004, the enablement rejection did not raise an issue with this term of claim 18. The only rejection which raised an issue with a hybridization term was in the first Office Action mailed on February 9, 2004. That rejection was for written description (possession, 35 U.S.C. 112, 1st paragraph) and specifically highlighted embodiments in claims 1 and 12. Applicants addressed that issue with claims 1 and 12 in their response filed on August 9, 2004 and the rejection was withdrawn in the Office Action of November 1, 2004. Certainly, if Applicants had recognized any explicit issue raised regarding the "hybridizes" term of claim 18, Applicants would have addressed that issue in either the response filed on August 9, 2004 or in the response filed on January 3, 2005. Both enablement rejections indicated to Applicants only that claim 18 was included merely due to its dependency on claim 1, which contained all the phrases for which the Examiner raised issues and which Applicants cite herein. Applicants note that claim 18 is an Original claim, present at the time of filing this application. Applicants do not understand how the Examiner considers an issue raised on an Original claim only during comments accompanying an Advisory action, and apparently not in two previous office actions, to be a maintained rejection. Applicants respectfully invite the Examiner to point out where either enablement rejection raised an issue with the "hybridizes" term of claim 18. Applicants further welcome any suggestions the Examiner would like to make by telephone to address this "hybridizes" term in claim 18.

## Conclusion

The foregoing Remarks in Response to the Advisory Action are being provided to respectfully request that the Examiner reconsider his refusal to enter the Amendment and Response After Final Rejection filed on January 3, 2005. Applicants submit that the Amendment and Response After Final Rejection addressed the issues raised by the Examiner in the Final Office Action and that any additional issues can be addressed by simple modifications to the amended claims if they are entered. Applicants encourage the Examiner to call me at 617-374-7679 or Jean Silveri at 617-679-7336 to discuss suitable modifications upon entering the claims.

This paper is being filed timely as a request for a one month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

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Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

February 1, 2005

MILLENNIUM PHARMACEUTICALS, INC.

Вv

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